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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,938	06/04/2002	Shinichiro Morita	SAEG108.001APC	4758

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action **Before the Filing of an Appeal Brief**	**Application No.** *10/070,938*	**Applicant(s)** MORITA ET AL.	
	Examiner David M. Naff	**Art Unit** 1651	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *7-11 and 15-19*.
   Claim(s) withdrawn from consideration: *None*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

David M. Naff
Primary Examiner
Art Unit: 1651

Continuation of 11. does NOT place the application in condition for allowance because: of the following reasons. Applicants state that the claims have been amended to require seeding the matrix with cells and culturing until the matrix is completely covered with the cells before embedding the matrix in vivo. However, as set in the rejection, Naughton et al disclose seeding a matrix with cells and producing in vitro tissue such as a tubular tissue structure, and implanting the tissue structure. In producing such a tissue structure, the matrix will be completely covered with cells or otherwise the structure not be formed.

Applicants urge that Vyakarnam et al use reinforcing fibers only in foam when regenerating bone or cartilaginous tissue. However, cardiovascular tissue can contain cartilaginous tissue. Furthermore, Vyakarnam et al disclose producing a scaffold for vascular repair, and recognize (col 1, lines 38-45) that it is known to use foam reinforced with fibers for repair of blood vessels (Hinsch et al ('898). It would have been obvious when Hinsch et al is also considered to reinforce a scaffold used to produce tissue structures in the form of blood vessels or arteries as taught by Naughton et al. While Vyakarnam et al may consider Hinsch et al to be deficient in certain aspects, this is not related to the use of reinforcing fibers, but because the foam of Hinsch et al lacks the anisotropic features of natural tissues. In fact, Vyakarnam et al state that the Hinsch foams had an advantage of having regular pore sizes and shapes that could be controlled by the processing conditions, solvents selected, and the additives (col 1, lines 40-45).

Applicants urge that Naughton et al criticizes the use of artificial reinforcing material in blood vessels. However, the invention as broadly claimed in claims 7-11 and 19 does not require a reinforcing material that is artificial. The bioabsorbable material of claims 7-11 and 19 can be connective tissue proteins that serve as a support as disclosed by Naughton et al. As to the other claims that require the reinforcement to comprise polylactic acid or polyglycolic acid, such reinforcement would have been obvious when Hinsch et al and the Japanese patent are considered which teach reinforcement with fibers that can be made of polylactic acid. The use of synthetic polymer fibers for reinforcement is clearly obvious as an alternative to extracellular matrix protein such as elastin and collagen produced by cells that provide support in the matrix of Naughton et al. Naughton et al is not applied alone, but in combination with other references, and the references must be considered together as a whole rather than each alone. It would have been well within the ordinary skill of the art to select between two alternatives of providing support to a foam matrix. While Hinsch et al and the Japanese patent may not seed the foam with cells before implanting, seeding with cells is suggested by Naughton et al, as well as Vyakarnam et al (paragraph bridging cols 18 and 19), to provide a matrix containing tissue or cells in vitro prior to implanting. It is granted that the Japanese patent discloses that the scaffold (filler material) breaks down and is absorbed into the body after tissue is formed. However, the matrix of the present claims is bioabsorbable and will break down and be absorbed into the body when tissue is regenerated in vivo after implanting.

Contrary to applicants' assertion, there is no suggestion by the references that using artificial reinforcing fibers in a matrix seeded with cardiovascular cells will make the matrix too stiff or impede the development of the cardiovascular tissue. If too great a stiffness occurred, Vyakarnam et al, Hinsch et al and the Japanese patent would not have disclosed providing support for a sponge or foam to be implanted with synthetic polymer fibers. If the fibers impeded the development of tissue, the references would not have used the reinforcing fibers since the matrix of the references serves as a support for cells to form tissue even when the matrix is implanted without seeding with cells in vitro. After implanting, cells infiltrate the scaffold and form tissue in vivo. .